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EXAMINER	
CRANDALL, LYNSEY P	
ART UNIT	PAPER NUMBER
3769	

NOTIFICATION DATE	DELIVERY MODE
10/06/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/776,688	ALTSHULER ET AL.	
	Examiner	Art Unit	
	LYNSEY CRANDALL	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,6,9,15-19,23,24,26,28-30,48-86 and 88-112* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *18* is/are allowed.

6)☒ Claim(s) *1,5,6,9,15-17,19,23,24,26,28-30,48-86 and 88-112* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/12/2010, 8/19/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 7/12/2010 have been fully considered but they are not persuasive.

2. Regarding the 112 rejection of claims 53-56 and 74-77, applicant argues that because applicant has disclosed values for energy density and irradiation time in the specification that would result in a power density of 1 W/cm^2, the rejection is improper. While the specification does various energy parameters, it still does not give applicant support for claiming the particular range of values for the power density. Applicant has given no criticality to a power density of 1 W/cm^2, an energy density of 10 $Joules/cm^2$ nor an irradiation time of 10 seconds. In the case law (*Kolmes*) cited by applicant, the reference clearly states that the value claimed in the range is preferable. Applicant has done no such thing with the values currently claimed. Applicant is picking and choosing values disclosed in the specification to arrive at a value of 1 W/cm^2 when this value is clearly not discussed at all in the specification. It appears that applicant is narrowing the ranges for power density in order to get around the prior art of record without having support for the newly claimed ranges including why this range is critical to the method. Therefore, the examiner upholds the new matter rejection.

3. Regarding claim 1, applicant argues that Zharov does not disclose irradiating a region of facial tissue below an area of facial skin by directing radiation from the phototherapy device applicator to penetrate the mucosal lining of the oral cavity of the oral cavity to the region. The examiner respectfully disagrees. As clearly cited by

applicant on page 16 of the arguments, the device (15) taught by Zharov is used to ***irradiate the whole mouth***, specifically the oral cavity. Using the broadest reasonable interpretation, the examiner contends that since the whole mouth is being irradiated at least some of this radiation will penetrate a mucosal lining of the oral cavity, since the mucosal lining is part of the mouth. Applicant also states that there is no reason to believe that the use of the phototherapy device (15) would inherently result in the treatment of facial skin. Again, the examiner respectfully disagrees. Zharov clearly teaches all the same method steps as claimed by applicant and therefore the result of these method steps is the same. Where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex Parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993). It is the examiner's position that the Zharov device inherently treats blood within the mouth and also provides a dermatological treatment, since the reference clearly teaches irradiating the inside of the mouth in the same manner claimed by applicant. Applicant argues that Zharov doesn't specifically disclose using the treatment parameters within the oral cavity. It is the examiner's position that the treatment parameters disclosed by Zharov are implemented with any of the various embodiments that treat different parts of the body, as seen in Fig. 2. Zharov clearly states that the application of the device is to implement light-therapy to treat various extensive pathologies on the bioobject including dermatology, cosmetology; the treatment of traumas, bruises, oedemas, varicose veins,

blood therapy, treatment of infectious processes (abstract). One such bioobject includes the oral cavity (15, Figs. 2 and 2a). It is the examiner's position that by using the treatment parameters disclosed in the Zharov reference, the phototherapy device (15) treats any number of the various extensive pathologies discussed by Zharov that occur in the oral cavity or the face. These treatments include blood therapy of blood located in the mouth, cosmetic/dermatological treatment of the facial region, immune system treatment to fight diseases located in the mouth, etc. Therefore, applicant's arguments are not considered persuasive.

4. Regarding claim 78, Zharov discloses a range of wavelengths including red and infrared light, specifically from 630nm to 800nm. Furthermore, Zharov discloses the use of wavelengths from ultra-violet to radio (claims 1). Applicant discloses the wavelength of 630nm to be beneficial for microcirculation (Par 0121) and also discloses that heat (infrared light) can have a therapeutic effect on tissue (Par 0074). Therefore, Zharov discloses the use of wavelengths that cause both an increase in microcirculation and a therapeutic effect. With regards to applicant's arguments that Zharov does not disclose concurrently irradiating the treatment area with multiple wavelengths, the examiner respectfully disagrees. Zharov clearly discloses that a control unit provides the switching of sources with different spectrum ranges (wavelengths) in accordance with a given program, for example it can provide their separate or ***simultaneous*** operation (Col 2, lines 44-51). Therefore, applicant's arguments are not considered persuasive.

5. Regarding claim 97, applicant argues that Zharov does not disclose irradiating a subject's oral cavity for a sufficiently long time so as to expose substantially ***an entire***

volume of the subject's blood to radiation in one or more sessions. Applicant has not disclosed in the specification how long it would take to expose an entire volume of the subject's blood nor how many treatment sessions this would take, furthermore applicant has not defined "an entire volume of the subject's blood". The only mention of an "entire volume" of blood is in the original claim 27. Therefore, it is the examiner's position, using the broadest reasonable interpretation, that the entire volume of blood is the entire volume of blood present within the ***oral cavity*** at the time of treatment. Since Zharov teaches irradiating the entire mouth, it is the examiner's position that substantially all of blood located in this treatment area at the time of treatment is exposed to radiation. Furthermore, applicant has not defined substantially. Zharov clearly teaches similar treatment times as those disclosed by applicant and also discloses the need for multiple, repetitive treatments. Therefore, applicant's arguments are not considered persuasive.

6. Regarding claim 53, as discussed above, applicant does not have support in the specification for the use of a power density of 1 W/cm^2 to about 10 W/cm^2. Specifically, applicant has given zero criticality or importance to the use of this higher power density. Due to the lack of criticality provided by applicant for the use of higher power densities, it is the examiner's position that it would have been obvious to try different power densities in order to provide the most effective results for the desired treatment. Perricone discloses the use of higher power densities for cosmetic/dermatological treatments. Therefore, the examiner maintains the position that it would have been obvious to try the higher power densities taught by Perricone in the device taught by

Zharov in order to provide a dermatological/cosmetic result if so desired. Therefore, applicant's arguments are not considered persuasive.

Priority

7. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, Application No. 10/680,705 and 10/702,104, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. These prior-filed applications fail to disclose treating the oral cavity, which is the basis for all the claims in the current application.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 53-56, 74-77 and 105-112 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. [Claims 53-56 and 74-77] The currently claimed power density range of 1 W/cm^2 to about 10 W/cm^2 is considered new matter. Applicant cites paragraph [0015] for support of this amendment. This paragraph reads “a range of about 10 $Joules/cm^2$ to about 100 $Joules/cm^2$, in the irradiated tissue. The treatment sessions, each of which last for about 10 seconds to about 1000 seconds." Clearly, the claimed power density ranges are not explicitly disclosed here, in fact in the same paragraph [0015] applicant discloses a range of 1 mW/cm^2 to about 10 W/cm^2. Applicant goes on to state that for a disclosed treatment time of 10 seconds, arbitrarily chosen from a treatment time in the range of 10 seconds to 1000 seconds, the resulting power density would be the claimed range of 1 W/cm^2 to about 10 W/cm^2. Randomly choosing a disclosed treatment time from a range of treatment times to provide a specific power density range is considered new matter. For instance, if applicant were to choose 1000 seconds, also a disclosed treatment time, the resulting power density range would be 10 mW/cm^2 to 100 mW/cm^2. The currently claimed range is not explicitly disclosed, and applicant gives no importance or criticality to the specific power density. Amending a range to distinguish

over a prior art reference is considered new matter if that range is not explicitly disclosed. Based on applicant's arguments, hundreds of power density ranges could be formulated by arbitrarily choosing a treatment time disclosed, none of which are given any criticality. If applicant amends claims to include a specific range from a disclosure of a broad range in order to overcome a prior art rejection, this is considered new matter (MPEP 2163.05).

11. [Claims 105-112] Applicant is claiming a power in a range of about 1W to about 10W, applicant has no support for this range in the disclosure. Applicant has support for a power of 1mW to 10W, preferably 10 mW to 1 W (Pars 0070, 0166) and a power of less than 10 W (original claim 5). Again, applicant has no given no criticality to the use of higher power ranges and has no support for this range of values.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 5-6, 9, 15-17, 19, 23, 24, 26, 28-30, 48-52, 57-73 and 78-112 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. 6,443,978 to Zharov.

14. Zharov discloses a light therapy device used to treat various extensive pathologies on the patient including dermatology, cosmetology, treatment of traumas, bruises, blood therapy and treatment of infectious processes (abstract). Zharov discloses a device (15, Fig. 2 and 2A) that is placed in the oral cavity of a patient and irradiated with diodes (1, Fig. 2A). The device includes a plurality of radiation sources emitting radiation at one or more wavelengths in the range from ultraviolet to radio (claim 1), specifically 630 nm to 800 nm, having a power density of up to 200 mW/cm^2 (Col 4, lines 10-14) and a treatment time from 10 minutes to 50 minutes (claim 64). Zharov discloses multiple treatment sessions, specifically six procedures lasting 15 minutes each within one week (Col 12, lines 8-10).

15. Zharov discloses a power density of 2 mW/cm^2 to 200 mW/cm^2 and a treatment time from 10 minutes to 50 minutes (claim 64). Using a power density of 2 mW/cm^2 (.002 W/cm^2) and a treatment time of 10 minutes (600 seconds), results in an energy flux of 1.2 $Joules/cm^2$ (.002 W/cm^2 * 600 seconds). Similarly, Using a power density of 20 mW/cm^2 (.02 W/cm^2) and a treatment time of 10 minutes (600 seconds), results in an energy flux of 12 $Joules/cm^2$ (.02 W/cm^2 * 600 seconds). Zharov discloses using diodes having a power of 0.5 to 5 Watts (Col 4, 35-37). Zharov discloses using infrared radiation in addition to visible radiation in order to heat tissue (Col 4, lines 35-41). Zharov discloses biological sensors to allow feedback and monitoring of the treatment (Col 2, lines 44-51). Zharov discloses the use of light emitting diodes with a power of 1 Watt (claim 18).

16. Wavelengths of the sources are chosen on the basis of the absorption wavelengths of biomolecules of both exogenous and endogenous origins (Col 2, lines 4-7); these endogenous biomolecules are interpreted as light acceptors. The type or location of the light acceptors does not affect the claimed method steps of irradiating the oral cavity. Zharov discloses irradiating the oral cavity with similar wavelengths, power density, treatment time and energy flux. Inherently Zharov's method irradiates the blood and deposits a dose of radiation below an area of facial skin. Since these light acceptors exist naturally within the blood in the oral cavity, Zharov's method would target them as well. Where a reference discloses the terms of the recited method steps, and such steps necessarily result in the desired and recited effect, that the reference does not describe the recited effect *in haec verba* is of no significance as the reference meets the claim under the doctrine of inherency. Ex Parte Novitski, 26 USPQ2d 1389, 1390-91 (BdPatApp & Inter 1993). For example, Zharov's method inherently produces a dermatological or cosmetic result.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 53-56 and 74-77 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. 6,443,978 to Zharov and further in view of U.S. 2003/0009158 to Perricone.

20. Zharov is discussed above, but is silent with regards to a specific power density. Perricone discloses a dermatological or cosmetic treatment of the mouth region (Par 0015 and abstract) using light having a power density of more than 800 mW/cm^2 (Par 0019 and Claim 3). It would have been obvious to a person having ordinary skill in the art at the time of applicant's invention to use the power density disclosed by Perricone in the method taught by Zharov as it is an effective power density for dermatologically treating the mouth region of a patient.

Allowable Subject Matter

21. Claim 18 is allowed.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LYNSEY CRANDALL whose telephone number is (571)270-7035. The examiner can normally be reached on Monday to Thursday 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Hank Johnson can be reached on (571)272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LYNSEY CRANDALL/
Examiner, Art Unit 3769

9/30/2010

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769